Special 510(k) Summary of Safety and Effectiveness: Line Extension to the Xia® 4.5 Spinal System

Submission Information

Name and Address of the Sponsor of the 510(k) Submission:	Stryker Spine 2 Pearl Court Allendale, NJ 07401
Contact Person:	Simona Voic Sr. Regulatory Affairs Project Manager Stryker Spine 2 Pearl Court, Allendale, NJ 07401 Tel: (908) 522 - 3482
Date of Summary Preparation:	February 27, 2012 Revised

Device Identification

Proprietary Name:	Xia® 4.5 Spinal System
Common Name:	Spinal Fixation Appliances
Classification Name and Reference:	Spinal Interlaminal Fixation Orthosis, 21 CFR §888.3050 Spinal Intervertebral Body Fixation Orthosis 21 CFR §888.3060 Pedicle Screw Spinal System 21 CFR §888.3070
Device Product Code:	87 KWP: Appliance, Fixation, Spinal Interlaminal 87 KWQ: Appliance, Fixation, Spinal, Intervertebral Body 87 MNH: Spondylolisthesis Spinal Fixation System 87 MNI: Orthosis, Spinal, Pedicle Fixation
Predicate Device Information:	K050461 - Xia® 4.5 Spinal System

Predicate Device Identification

The Stryker Spine Xia® 4.5 Spinal System is comprised of Ø 4.5 mm rods, Polyaxial and Monoaxial bone screws, Blockers, Hooks, Dual Staples, and Connectors. The components are available in a variety of diameters and lengths in order to accommodate patient anatomy and are fabricated from titanium alloy. The implants are provided non-sterile and are used for either posterior or anterolateral non-cervical spinal fixation.

Description of Device Modification

This submission is intended to address a line extension to Xia® 4.5 Spinal System. The line extension includes a new range of Titanium alloy connectors.

Intended Use:

The XIA® 4.5 Spinal System is intended for posterior noncervical pedicle fixation for the following indications: severe spondylolisthesis (i.e. Grades 3 and 4 at L5-S1 or degenerative spondylolisthesis with objective evidence of neurologic impairment), trauma (i.e. fracture or dislocation), spinal stenosis, curvatures (i.e. scoliosis, kyphosis, and/or lordosis), tumor, pseudoarthrosis and failed previous fusion.

The XIA® 4.5 Spinal System is also intended for anterolateral and posterior, non-cervical, non-pedicle fixation for the following indications: degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies), spondylolisthesis, trauma (i.e. fracture or dislocation), spinal stenosis, curvatures (i.e. scoliosis, kyphosis, and/or lordosis), tumor, pseudoarthrosis and failed previous fusion.

The XIA® 4.5 Spinal System is intended to provide additional support during fusion using autograft or allograft in skeletally mature patients only.

Statement of Technological Comparison:

The subject components share the same intended use, material, and basic design concepts as that of the predicate device: Xia® 4.5 Spinal System (K050461). Mechanical testing also demonstrated comparable mechanical properties to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Stryker Spine
% Ms. Simona Voic
Senior RA Project Manager
2 Pearl Court
Allendale, New Jersey 07401

MAR 16 2012

Re: K052761
Trade/Device Name: XIA® 4.5 Spinal System
Regulation Number: 21 CFR 888.3070
Regulation Name: Pedicle Screw Spinal System
Regulatory Class: II
Product Code: MNI, MNH, KWP, KWQ
Dated: September 29, 2005
Received: September 30, 2005

Dear Ms. Voic:

This letter corrects our substantially equivalent letter of October 11, 2005.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K052761

Device Name: Xia® 4.5 Spinal System

Indications For Use:

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Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K052761